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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,002	10/30/2000	George M. Johnson	1065-011us04	7813

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EXAMINER	
LACYK, JOHN P	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TP

Office Action Summary	Application No.	Applicant(s)	
	09/702,002	JOHNSON ET AL.	
	Examiner	Art Unit	
	John P. Lacyk	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-28,31,32 and 34-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14,16,19,20,22,23,27,28,32 and 34-37* is/are rejected.

7)☒ Claim(s) *11-13,17,18,21,24-26 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-10, 14, 16, 19, 20, 22, 23, 27, 28, 32 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Silverman et al. ('063) cited by Applicant. Silverman et al. ('063) teach a method of implanting a bulking device beneath mucosa in the lower esophagus comprising the steps of: puncturing the mucosa with a device having a first cross sectional area (see Figure 2); creating a pocket beneath the mucosa by introducing a volume of fluid, wherein the fluid comprises saline or contrast media (see column 11, lines 10-29) within the range of from about 0.5 cc to about 5 cc of fluid beneath the mucosa (see column 15, lines 33-39), wherein the introducing a volume of fluid is accomplished using an injection needle, wherein the needle is within the range of from about 18 gauge to about 30 gauge (see column 5, lines 16-21), and in communication with the puncture; enlarging the puncture; and introducing a hydrogel,

which is inherently expandable in response to exposure to fluid, bulking device (see column 9, lines 54-66) through the puncture and into the pocket (see Figures 7 and 8; column15, lines 23-39), wherein the bulking device is expandable from an introduction cross sectional area to an enlarged cross sectional area, and the introduction cross sectional area is greater than the first cross sectional area (see figures 7 and 8; and column 19, lines 31-34). Also, Silverman et al. ('063) teach a method of removing the bulking device from the pocket, which is accomplished by creating (establishing) a passageway through tissue (mucosa) to the bulking device, by introducing a solvent DMSO to dissolve the bulking device, by using a sharpened instrument (needle) (see column 19, lines 20-34); by using an endoscope (see column 4, lines 17-30). A step of locating the bulking device is an inherent step of the method of explanting said bulking device.

4. Claims 17-18 are objected to because of the following informalities: Claim 17 depends from cancelled claim 15. Appropriate correction is required.

5. Applicant's arguments filed 11/18/05 have been fully considered but they are not persuasive. Applicant argues that Silverman et al does not teach "enlarging the puncture". As shown in Figures 3 and 4 and discussed on column 5, lines 25-45 and column 15, lines 22-65 the needle 61 would "puncture" the mucosa when tip 67 or 76 penetrates the mucosa, since the needle would be inserted until the openings,71 were within the enlargement or pocket in order to introduce the augmenting or bulking

solution, the puncture would inherently be enlarged by the further insertion of the needle since the diameter of the needle where the openings are is larger than the diameter at the tip where the puncturing of the mucosa would occur. Applicant also argues that Silverman et al fails to teach an expandable hydrogel bulking device. Applicant argues that Silverman does not provide any teaching whether the hydrogel is hydrated prior to implantations or subsequent to implantation, however claim 14 only claims positioning an expandable hydrogel and does not limit the hydrogel to expanding only after being implanted and Silverman et al clearly discloses the use of a hydrogel as one known bulking agent. Further applicant states that "inherency requires that one skilled in the art would necessarily understand the applied reference to include the missing disclosure", as in this case the one skilled in the art would necessarily understand the reference as providing a bulking device to increase the bulk of the cavity to treat GERD would include an expandable device to provide the "bulking" and further the use of "expandable" hydrogels are well known for use in the body. Therefore one skilled in the art would necessarily understand the reference to include an expandable hydrogel. Applicant argues that Silverman does not teach explanting the bulking device through a tunnel created by a cutting tool by applying a force. Silverman teaches (column 19, lines 28-30) that the mucosal layer can be incised to release the implant, which clearly teaches using a cutting tool to create an incision or a "tunnel" through the mucosa to allow the device to be removed. Clearly "a force" of some kind would inherently be needed to remove the device since the device would not just fall out, the device would need to be pulled or pushed out which would inherently be "a force".

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Guittard et al is cited to further show the use of expandable hydrogels used in the body.

4. Claims 11-13, 17-18, 21, 24-26, 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571-272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John P Lacyk
Primary Examiner
Art Unit 3735

J.P. Lacyk